# CITROMA- magnesium citrate liquid Vi-Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### Swan 164.000 164AA Rev 2

### **Active Ingredient**

Magnesium citrate 1.745g per fl oz

### **Purpose**

Saline laxative

#### use

for relief of occasional constipation (irregularity). Generally produces bowel movement in 1/2 to 6 hours

### Warnings

for this product

#### **Ask A Doctor**

# before use if you have

- kidney disease
- a magnesium restricted diet
- abdorominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks
- already used a laxative for a period longer than 1 week

# Ask a doctor or pharmacist

**before use if you are** taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work.

# Stop use

and ask a doctor if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.

#### if pregnant or breast-feeding

ask help professional before use.

### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Store at temperatures betweem 46° and 86°F (8° and 30° C)

#### **Directions**

- shake well before using
- drink a full glass (8 ounces) of liquid with each dose
- may be taken as a single daily dose or in divided doses

adults and children 12 years of age and over - 6.5 to 10 fl oz in 24 hours children 6 to under 12 years of age - 3 to 7 fl oz maximum 7 fl oz in 24 hours children 2 to under 6 years of age - 2 to 3 fl oz in 24 hours children under 2 years of age - ask a doctor

#### other information

• each fl oz contains: magnesium 290 mg

• each fl oz contains: **sodium 1 mg** 

# Inactive ingredients

benzoic acid, citric acid, disodium EDTA, flavor, sucralose, water

#### **Adverse Reaction**

Distributed by: Vi-Jon, LLC One Swan Drive, Smyrna, TN 37167

# principal display panel

**SWAN** 

**VERY LOW SODIUM** 

Citroma

MAGNESIUM CITRATE

#### cherry

- Saline Laxative
- Oral Solution

• Saccharin free

Do not use if tamper evident twist-off cap is missing, broken or separated from neckring 10 FL OZ (296 mL)



# CITROMA

magnesium citrate liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0164	
Route of Administration	ORAL			

	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
- 11		MAGNESIUM CITRATE	1.745 g in 29.6 mL

Inactive Ingredients			
Ingredient Name	Strength		
BENZOIC ACID (UNII: 85KN0B0MIM)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
water (UNII: 059QF0KO0R)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:0869- 0164-38	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/18/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	02/18/2018		

# **Labeler -** Vi-Jon, LLC (790752542)

# Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(0869-0164)	

Revised: 4/2021 Vi-Jon, LLC